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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/088,412	03/20/2002	Herbert Markl	DEAV1999/S009 US PCT	5276
5487	7590	09/13/2007		
ANDREA Q. RYAN SANOFI-AVENTIS U.S. LLC 1041 ROUTE 202-206 MAIL CODE: D303A BRIDGEWATER, NJ 08807			EXAMINER NAFF, DAVID M	
			ART UNIT 1657	PAPER NUMBER
			NOTIFICATION DATE 09/13/2007	DELIVERY MODE ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/088,412	Applicant(s) MARKL ET AL.	
	Examiner David M. Naff	Art Unit 1657	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 2/13/07 & 6/25/07.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 39-45, 48, 49, 52, 55-58, 60-69, 81, 82, 84, 85 and 89-92 is/are pending in the application.
- 4a) Of the above claim(s) 81, 82, 84, 85 and 89-92 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 39-45, 48, 49, 52, 55-58 and 60-69 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Claims in the application are 39-45, 48, 49, 52, 55-58, 60-69, 81, 82, 84, 85 and 89-92.

A response of 6/25/07 to a restriction requirement of 4/26/07
5 elected Group I claims 39-45, 48, 49, 52, 55-58 and 60-69 with
traverse.

The traverse urges that the inventions of Groups II and III
require the same special technical since both require membranes as
shown by Fig. 4. The traverse is persuasive with respect to Groups II
10 and III, and the claims of these groups are combined to form a single
group. The restriction of the claims of Group I from the claims of
Groups II and III is maintained, and is made final.

Claims 81, 82, 84, 85 and 89-92 are withdrawn from further
consideration pursuant to 37 CFR 1.142(b), as being drawn to a
15 nonelected invention, there being no allowable generic or linking
claim. Applicant timely traversed the restriction (election)
requirement in the reply filed on 6/25/07.

Claims 39-45, 48, 49, 52, 55-58 and 60-69 are examined on the
merits.

20 The text of those sections of Title 35, U.S. Code not included in
this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

Claims 42, 52, 55, 56, 60 and 69 are rejected under 35
U.S.C. 112, second paragraph, as being indefinite for failing to
25 particularly point out and distinctly claim the subject matter which

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applicant regards as the invention for reasons set forth in the previous office action.

Claim 42 is confusing by requiring introducing the second gas into the dialysis fluid in the container for the dialysis fluid since
5 claims 39 and 41 require introducing the second gas into the culture fluid. Introducing the second gas into the dialysis fluid cannot replace introducing the gas into the culture fluid since this is required in claims 39 and 41 on which claim 42 depends. If claim 42 is providing in the dialysis fluid the second gas that diffuses across
10 the membrane into the culture fluid from the dialysis fluid in claim 41, this should be made clear.

Claim 52 is unclear as to the material that is "Cuprophane". Cuprophane appears to be a tradename, and the specific material represented by the tradename is uncertain. While the specification
15 discloses that Cuprophane is regenerated cellulose (page 9, line 17), Cuprophane appears to be a specific form of regenerated cellulose, and the specific form is uncertain.

Claims 55 and 56 are unclear by reciting "area/surface ratio" since "m² per liter" is "area/volume ratio".

20 Claim 60 is unclear by not having clear antecedent basis for "the space" (line 2).

Claim 69 is unclear as to the meaning and scope of "harvesting the cells" relative to the steps of claim 39. If claim 69 is requiring separating cells from the culture fluid after culturing
25 cells in claim 39, this should be made clear by specifying that cells

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are separated from the culture fluid and specifying where in the process of claim 39 the cells are separated from the culture fluid.

Claim Rejections - 35 USC § 103

Claims 39-45, 48, 49, 52, 55-58 and 60-69 are rejected under 35
5 U.S.C. 103(a) as being unpatentable over Portner et al (listed on form PTO-1449).

The claims are drawn to a method for culturing cells using a reaction system comprising a container for dialysis fluid, a culture vessel for culturing cells and a membrane module. The module contains
10 a tube-shaped dialysis membrane. Dialysis fluid is circulated through the dialysis fluid container and the membrane module outside of the tube-shaped dialysis membrane. Culture fluid containing cells is circulated through the culture vessel and the membrane module inside the tube-shaped dialysis membrane. A first gas is introduced into
15 culture fluid in the culture vessel, and a second gas is introduced into culture fluid inside the tube-shaped dialysis membrane.

Portner et al disclose (Figure 2a, page 405) a reaction system as required by the present claims except for supplying gas to culture fluid in the dialysis module (membrane module). Portner et al
20 disclose (page 404, right col, 3rd complete paragraph) that when cells are pumped through the external module, the cells can suffer from oxygen limitation. Figure 3a (page 406) discloses a reactor without an external module where a culture chamber is separated from a dialyzing chamber by a dialysis membrane. Air is supplied to the

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culture chamber. In Figure 3b, air is supplied to the dialyzing chamber.

It would have been obvious to supply air to space containing circulating culture liquid containing cells in the dialysis module of the reactor of Figure 2a of Portner et al to prevent cells from suffering oxygen limitation as disclosed on page 404 since it would have been apparent from Figure 3a that oxygen can be supplied to cells in a chamber separated from a dialyzing chamber by a dialysis membrane. The conditions of dependent claims not disclosed by Portner et al are conditions that would be expected to require control when using the reaction system of Portner et al, and such conditions would have been matters of optimization depending on individual preference well within the skill of the art. Providing air to the dialyzing chamber as required by certain claims would have been suggested by Figure 3b of Portner et al.

Response to Arguments

The amendment of 2/13/07 urges that the claims require a 3-component system, and this system is different from the single vessel of Fig. 3 of Portner et al. However, Fig. 2a of Portner et al discloses a 3-component system, and the rejection is based on modifying the 3-component system of Fig. 2a. Supplying air to the culture chamber to provide oxygen for cells in Fig. 3 would not be expected to be limited only to when the culture chamber and dialysis membrane are in a single vessel. Fig. 2a shows a tube-shaped dialysis membrane. There is seen nothing to lead one to believe air cannot be

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supplied to cells in culture fluid in the dialysis module of Fig 2a analogous to supplying air to cells in culture fluid in contact with a dialysis membrane in Fig 3a. Portner et al disclose the problem that suspended cells can suffer from oxygen limitation when pumped through the external module. Supplying oxygen to cells in the module would have been clearly an obvious way of overcoming the oxygen limitation problem since Fig 3a shows supplying oxygen to cells on one side of a dialysis membrane.

The amendment urges that there is not motivation for the modification of Fig. 2a set forth above. However, Portner et al disclosing the problem that suspended cells can suffer from oxygen limitation when pumped through the external module would have been motivation to supply oxygen to cells in the dialysis module of Fig. 2a.

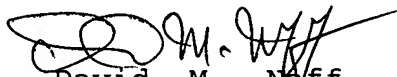
Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David M. Naff whose telephone number is 571-272-0920. The examiner can normally be reached on Monday-Friday 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


David M. Naff
Primary Examiner
Art Unit 1657

DMN

15 9/3/07